

## 5. 510(k) Summary

K113872

MAR - 8 2012

Page 1 of 2

**vidacare**4350 Lockhill Selma Road  
Shavano Park, TX 78249+2095  
210-375-8500**SUMMARY**

Submitter's name: Vidacare Corporation  
 Address: 4350 Lockhill Selma Road  
 Shavano Park, TX 78249  
 Phone: 210-375-8500  
 Fax number: 210-375-8537

Name of contact person: Grace Holland  
 Regulatory Specialists, Inc.  
 3722 Ave. Sausalito  
 Irvine CA 92606  
 Telephone: 949-262-0411  
 Fax: 949-552-2821

Date the summary was revised: February 24, 2012

Name of the device: The OnControl™ Bone Access and Bone Biopsy System  
 by Vidacare®  
 Trade or proprietary name: The OnControl™ Bone Access and Bone Biopsy System  
 by Vidacare®  
 Common or usual name: Cement Dispenser Conduit for Vertebroplasty and Bone  
 Biopsy Needle  
 Classification panel: Orthopedic Spine Devices Branch

Product Code	Classification Regulation	Classification Name
OAR	888.4200	Injector, vertebroplasty
MOQ	878.4820	Battery, replacement, rechargeable
KNW	876.1075	Instrument, biopsy

The legally marketed devices to which we are claiming equivalence [807.92(a) (3)]:

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K112468	The OnControl™ Bone Access System by Vidacare®	Vidacare Corp.
2	K022169	Clearview Plus Bone and Vertebral Body Biopsy Needles	Parallax Medical
3	K962425	The Bonoptoy® Coaxial Bone Biopsy System with Eccentric Drill	AprioMed

Page 27<sup>(3)</sup>**Description of the device:**

The OnControl Bone Access and Bone Biopsy System by Vidacare® consists of a reusable Power Driver and a disposable sterile needle set in a sealed tray. The sealed tray contains 1 coupler with driver sterile sleeve, 1 beveled needle set and 2 sharps protectors. The OnControl Bone Access System Needle Set is an 11 gauge, 152 mm cannula made of 304 stainless steel, with beveled cutting tip and stylet. The biopsy and vertebroplasty needle are the same needle. The needle sets are identical in gauge, length and materials to the predicate devices: the OnControl Bone Access System (cleared via K112468, The OnControl Bone Access System by Vidacare®) and 11g, the same as Clearview Plus Bone and Vertebral Body Biopsy Needles (cleared via K022169). The powered driver is identical to the predicate driver cleared via K112468, The OnControl Bone Access System by Vidacare®.

Under fluoroscopic imaging guidance, activation of the driver assists the clinician to insert the needle set through the cortex of the bone, into the vertebral body or area of lesion. The driver is then separated from the hub of the needle set by retracting the OnControl Connector release mechanism ring on the OnControl Connector. The needle set consists of two parts, an 11g outer cannula (3.05mm x 197mm) with an inner stylet (diameter of 2.54mm). The inner stylet is used only to penetrate the cortex and is then removed. A standard Luer lock (part of the 11 gauge cannula) permits attachment of the syringe for aspiration. The driver is activated and advanced to obtain the biopsy specimen and then withdrawn.

The driver is then separated from the needle assembly for specimen removal.

**Indications:**

The OnControl Bone Access and Bone Biopsy System is intended for use with a standard cement delivery system for the fixation of fractures of the vertebral body using vertebroplasty and/or for bone biopsy of the vertebral body and bone lesions.

**Summary of the technological characteristics of our device compared to the predicate device:**

The predicates and The OnControl™ Bone Access and Bone Biopsy System were compared in the following areas and found to have similar characteristics with one or more of the predicates and to be equivalent.

**Anatomical sites**

Biocompatibility  
Dimensional specifications  
Driver design features  
Energy type  
Environmental specifications  
Ergonomics of the patient-user interface  
Firmware  
Indication for Use



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Vidacare Corporation  
% Regulatory Specialists, Inc.  
Ms. Grace Holland  
3722 Avenue Sausalito  
Irvine, California 92606

MAR - 8 2012

Re: K113872

Trade/Device Name: The OnControl™ Bone Access and Bone Biopsy System by  
Vidacare®

Regulation Number: 21 CFR 876.1075

Regulation Name: Gastroenterology-urology biopsy instrument

Regulatory Class: II

Product Code: KNW

Dated: December 30, 2011

Received: December 30, 2011

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

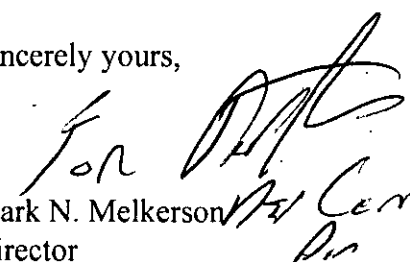
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

#### 4. Indications for Use Statement

Device Name: The OnControl™ Bone Access and Bone Biopsy System by  
Vidacare®

Device 510(k) number: K113872

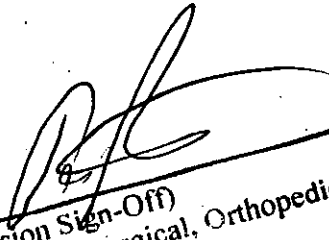
##### Indications for Use:

The OnControl Bone Access and Bone Biopsy System is intended for use with a standard cement delivery system for the fixation of fractures of the vertebral body using vertebroplasty and/or for bone biopsy of the vertebral body and bone lesions.

Prescription Use   X   AND/OR Over-The-Counter Use             
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices  
510(k) Number   K113872